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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,329

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Hugh Herr

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EXAMINER

FLORY, CHRISTOPHER A

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/671,329	Applicant(s) HERR ET AL.	
	Examiner CHRISTOPHER A. FLORY	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 13 November 2007 have been fully considered but they are not persuasive. Claims 1, 2, 4, 10, 11, 19, 20, 22, 29 and 30 stand rejected under 35 U.S.C. 102(b) as being anticipated by Beard'296. Claim 24 stands rejected under 35 U.S.C. 102(b) as being clearly anticipated by Stein'332. Claim 24 stands rejected under 35 U.S.C. 102(e) as being clearly anticipated by Swain'757. Claims 1-9, 11-23, 25-29 and 32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Johnson'693. Claims 1-4, 6-8, 11-23, 25-30 and 32 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Horst'882. Claims 6-8 stand rejected under 35 U.S.C. 102(b) as anticipated by Beard'296 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Beard'296. Claim 9 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Beard'296 in view of Swain'757 or in view of Naft'503.
2. The Examiner likewise thanks Mr. Pierce, Mr. Cass and Dr. Herr for their time and effective discussion of the claims as they relate to that which is considered the patentable material of the instant application. The Examiner suggested therein that to overcome the art, the claims could be amended to convey that the impedance is being modulated continuously or at least successively throughout a swing phase and walking cycle to better state the inventive concept of adaptive/updating/variable/learning modulation of ankle impedance or stiffness or damping throughout the gait cycle. However, the claims as presented in the amendment of 13 November 2007 lack

language to speak to this aspect of updated, variable, or adaptive modulation of stiffness control throughout a series of gait cycles, merely reciting modulation during walking. In its broadest reasonable interpretation, the recitation of "walking" simply means that the event occurs at some point while a patient is ambulatory, not that the modulation is updated or varied in a specific and adaptive manner at specific points throughout the gait cycle, such that being modulated during walking would require only a teaching of a singular, non-adaptive change in the variable at any arbitrary point during a walking movement.

3. Given this broad but reasonable interpretation of the claim language as presented, the applied references are still considered to read on the claims. For example, Swain and Stein both still can be considered to anticipate the modulation of ankle stiffness or damping during a walking event as previously explained. For the same reasons, the push-pull arrangement of Johnson is still considered to validly anticipate the rejected claims, as is the motor-slip arrangement of Horst.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 4, 10, 11, 19, 20, 22, 29 and 30 stand rejected under 35

U.S.C. 102(b) as being anticipated by Beard et al. (US Patent 5,112,296, hereinafter Beard'296).

Regarding claims 1, 4 and 10, Beard'296 discloses a variable-impedance active ankle foot orthosis (title; abstract; column 3, lines 5-40; column 4, lines 20-25; column 5, lines 50-60) comprising an actuator coupled to a foot portion of the orthosis (Fig. 1, actuator 10; column 4, lines 1-5 and 25-30; column 5, lines 1-48) for modulating a joint stiffness or damping of an ankle joint during walking for treating an ankle foot gait pathology, wherein the pathology comprises drop foot (abstract; column 5, lines 38-60). It is noted that there is inherently a joint formed between the leg portion 4 and foot portion 2. Alternatively, the knee orthotic joint 8 can also be considered to anticipate the claims as written, since it is not specified that the joint be the ankle joint, but rather that the joint be related to treatment of an ankle foot gait pathology.

Regarding claim 2, Beard'296 discloses a torsional spring stiffness control and spring-damper positional control (Fig. 6; column 5, lines 1-48). It is also noted that the actuator controls the stiffness of the knee orthotic joint.

Regarding claim 11, a drop foot patient inherently has one or both of anterior or posterior muscle weakness. Therefore, the Beard'296 device inherently treats a patient having such conditions.

Regarding claims 19, 20 and 22, Beard'296 discloses a method of modulating joint stiffness or damping of an ankle joint of an orthosis during walking (abstract)

wherein the method includes adjusting the stiffness of the joint during controlled plantar flexion and minimizing impedance during late stance (column 1, lines 20-36; column 2, lines 10-67; column 5, lines 47-60). It is noted that the joint between the leg portion and foot portion inherently exists and is inherently modulated throughout gait. It is also noted that the impedance of the knee orthotic joint is modulated throughout the walking cycle, and therefore anticipated the claims.

Regarding claims 29 and 30, the spring disclosed in Beard et al is considered to be operatively coupled to the orthotic joint both at the ankle and to the knee orthotic joint (4). Beard'296 also discloses sensing one or more parameters of the orthotic joint (column 4, lines 60-68)

6. Claim 24 stands rejected, and claims 33-36 are rejected, under 35 U.S.C. 102(b) as being clearly anticipated by Stein (US Patent 5,643,332, hereinafter referred to as Stein'332).

Stein'332 clearly outlines a FES stimulation device and method which modulates ankle stiffness during the swing phase of a walking cycle, which inherently provides control during controlled plantar flexion and minimizes forefoot collision. Regarding the newly submitted claim limitation of modulation during swing phase, reference is specifically made to column 6, lines 34-55.

7. Claim 24 stands rejected, and claims 33-36 are rejected, under 35 U.S.C. 102(e) as being clearly anticipated by Swain et al. (US Patent 6,507,757).

Regarding claim 24 Swain et al. clearly discloses the invention as claimed (Figs. 1-6; abstract; column 2, lines 16-67; column 12, line 10 through column 14, line 10).

Regarding the newly submitted claim limitation of modulation during swing phase, reference is specifically made to column 1, lines 16-37; column 12, lines 27-43; and column 13, lines 3-50.

8. Claims 1-9, 11-23, 25-29 and 32 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Johnson et al. (US 5,662,693, hereinafter Johnson'693).

Particular emphasis is placed on the abstract; Figures 1, 3c, 5 and 9; column 8, lines 4-14; column 9, lines 3-27; column 10, lines 55-65.

Specifically regarding claim 5, the actuator shown in Figure 3c of Johnson'693 can be considered a series elastic actuator.

9. Claims 1-4, 6-8, 11-23, 25-30 and 32 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by Horst (US 6,966,882, hereinafter Horst'882).

Particular emphasis is given to the abstract, Figures 1, 4 and 6 and related paragraphs.

10. Claim 31 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Goffer (US 2003/0093021, hereinafter Goffer'021).

Emphasis is placed on paragraphs [6], [220], [221], [225] and [226] which describe a method of treating an ankle foot gait pathology using functional electrical stimulation in conjunction with a traditional orthosis or brace. It is noted that the amendment to the claim brought about this new ground of rejection.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 6-8 stand rejected under 35 U.S.C. 102(b) as anticipated by Beard'296 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Beard'296

Regarding claims 6 and 8, Beard'296 discloses an angle sensor (Fig. 4, radial resistor 24; column 4, lines 60-68; column 6, lines 18-36) capable of being used on the ankle. Furthermore, since a knee angle inherently has a correlated and consistent ankle angle during the standing phase, measuring the angle of the knee is synonymous with measuring the correlated ankle angle.

In the alternative, angle sensors are well known in the art, such as those described in Beard'296, Stein'332 and Horst (US Patent 6,966,882, hereinafter referred to as Horst'882), all of which are capable of being used on the ankle of a patient suffering drop foot. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Beard'296 device to monitor the ankle rather than the knee, because the knee angle is an equivalent measurement to the ankle angle in the control sense as discussed above.

Regarding claims 7 and 8, Beard'296 discloses EMG sensors which function as ground reaction force sensors (column 4, lines 50-60; column 5, line 59 through column 6, line 18). At foot strike, the musculature of the leg intuitively reacts to the impact by

increasing stimulation to the leg stabilizer muscles in order to absorb the force of the impact and balance the patient while walking. Thus, impact ground force is transferred quantifiably to contractions of the leg musculature that is being sensed by the EMG electrodes of the Beard'296 device.

In the alternative, ground reaction force sensors (or foot switches) are well known in the foot orthosis art and are described in Horst'882, Swain et al., and Naft et al. (US Patent 6,517,503). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Beard'296 with a ground reaction force sensor as described in the prior art cited above to provide the Beard'296 system with an accurate means of distinguishing the varying stages of the walking cycle to more accurately time activation of the orthosis to prevent the symptoms of drop foot.

13. Claim 9 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Beard'296 in view of Swain et al. or in view of Naft et al. (US Patent 6,517,503).

Regarding claim 9, Beard'296 discloses the invention substantially as claimed but does not expressly disclose a foot switch. In the same field of endeavor, Swain et al. teaches the use of a foot switch for sensing foot rise or foot strike in order to accurately deliver stimulation for treatment of drop foot (abstract). Additionally in the same field of endeavor, Naft et al. teaches use of a foot switch in an external orthosis device to selectively lock and unlock the knee joint in order to provide improved gait (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Beard'296 with the foot switch of either Swain et al. or Naft et al. to provide the Beard'296 system with the same advantage of

improving patient gait and treating drop foot (motivation to combine provided by the abstracts of Swain et al. and Naft et al.).

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

29 May 2008

/George Manuel/
Primary Examiner